REMARKS AND ARGUMENTS

This Amendment and Response is submitted in response to the Examiner's Office Action dated March 14, 2006. Claim 1 has been amended, and Claims 16 and 17 have been cancelled. Claim 18 is new. Accordingly, Claims 1-15 and 18 are pending in the current application. Reconsideration and withdrawal of the rejections of the claims are respectfully requested.

The Examiner has rejected Claims 1-8, 10-15 and 17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,617,016 to Bloomberg. Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bloomberg in view of U.S. Patent Application 2003/0000524 by Anderson et al. Additionally, Claims 16 and 17 have been rejected for failing to comply with the enablement requirement under 35 U.S.C. 112, ¶ 1.

The present invention is directed to an injection device for the delivery of medicament to a patient through a retractable needle. The device contains a needle, a barrel to hold a preloaded dose of medicament, a plunger axially movable within the barrel to drive the medicament through the needle and an energy source to drive the plunger and the barrel. The device includes an outer housing to contain the various components of the device and a movable inner housing. The energy source drives the plunger and the barrel by means of acting on an inner housing that in turn acts 1) on both the barrel and the plunger, 2) on the plunger but not the barrel, and 3) on neither the plunger nor the barrel. Additionally, the device contains a biasing means that biases the needle in a retracted position such that the needle is withdrawn inside of an outer housing.

The injection is preformed in a series of three stages or modes that all involve action of the inner housing. In a first mode the inner housing acts to drive the barrel and thus the needle forward against the biasing means. This accomplishes the injection by driving the needle out of the outer housing. In a second mode the inner housing acts to drive the plunger into the barrel, thus forcing the medicament out of the needle. In a third mode the inner housing acts to drive neither the barrel nor the plunger and remains in a position removed from the path of barrel and

the plunger. This allows the plunger, barrel and needle to retract inside the outer housing under the action of the biasing means.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-8, 10-15 and 17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,617,016 to Bloomberg. It is well recognized that claims are anticipated if, and only if, each and every element, as set forth in the claim is found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See MPEP § 2131. To constitute anticipation, all material elements of the claim must be found in one prior art source. In re Marshall, 198 USPQ 344 (CCPA 1978); In re Kalm, 154 USPQ 10 (CCPA 1967). Additionally, the elements of the reference must be arranged as required by the claim. In re Bond, 15 USPQ 2d 1566 (Fed. Cir. 1990). Applicant respectfully submits that the cited references do not teach all of the material elements and do not arrange the elements as required by the rejected claim language.

Bloomberg discloses a device that delivers an injection for a medical purpose by means of a hypodermic syringe. The device is operable to first load the syringe with medicament and then deliver the medicament to the injection site. These aspects of the invention are accomplished by a tension spring and an electric motor that drives a transmission system including a drive shaft, a series of gears, and two threaded screws that in turn drive elements that act the barrel and the plunger of the syringe.

Bloomberg does not disclose a device that contains a single component or element that in a first mode acts both on the barrel and the plunger of the syringe, in a second mode acts on only the plunger, and in a third mode acts on neither the barrel nor the plunger. Specifically, Bloomberg recites an inner part 16 that acts on the barrel of the syringe and a separate displacement means 34 that acts on the plunger of the syringe. During the loading of the device,

tension springs 55 disposed between the inner part 16 and the middle part 15 are loaded in preparation to drive the barrel of the syringe. The plunger is withdrawn from the barrel of the syringe both to draw medicament into the syringe and to place the displacement means in a position to drive the plunger during the injection. Fig. 11 shows a syringe that is loaded and ready for injection. The injection takes place as described in col. 8, lines 47-63:

> The device is now ready for insertion, which occurs by pulling the trigger 64, upon which under action of the tension springs 55 the inner part 16 together with the hypodermic syringe 4 is inserted until the spring ring 54 moves into its upper end position, which is determined by a contact 78 with which a portion 79 of the spring ring 54 cooperates (see Fig. 12). The hypodermic syringe with the needle thus penetrates to the necessary depth and through closure of the switch 75, which is achieved when the top cover 68 is pushed and the trigger 64 is pulled at the same time, injection occurs, that is, the motor 17 displaces the displacement means 34 and accordingly the plunger 10 of the hypodermic syringe 4 forward in such a way that the enclosed amount of insulin will be injected into the body tissue.

As is apparent from this description, the barrel and the plunger of the syringe are acted on by separate elements that are driven by separate means. Specifically, the barrel is acted on by the inner part 16 which is driven by tension springs 55. In contrast, the plunger is acted on by the displacement means 34 which is driven by the motor 17. These are clearly separate elements driven by different energy sources. As described above, the present invention recites a single element, namely the inner housing 7, that drives both the barrel and the plunger. It is respectfully asserted that the Examiner has not identified which part of the invention disclosed in Bloomberg is to be regarded as equivalent to the inner housing 7.

In addition to driving both the barrel and the plunger, the inner housing 7 allows the needle to retract after completion of the injection. As described above, this is achieved in a third mode of operation in which the inner housing acts on neither the plunger nor the barrel thus allowing the needle to retract under the action of the biasing means. In contrast, the invention

disclosed by Bloomberg does not provide for an automatic retraction of the needle. The manual retraction of the needle is described at col. 6, lines 20-23, and col. 9, lines 1-2:

> [W]hich happens when the middle part shall be brought back to its retracted position. This will be done manually after the injection device has performed its operation.
>
> . . . .
> The middle part can be manually pushed inside the housing 14, in which position the barrel part 6 of the hypodermic syringe 4 will be released from its holding position. . . .

The Bloomberg reference does not contain each and every element set forth in the claims of the present application. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested. In particular, Bloomberg fails to disclose at least the following italicized features of independent Claim 1:

> 1. An injection device comprising an outer housing inside which is located
>
> a barrel for holding a dose of a medicament;
>
> a needle at one end the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of said outer housing but is biased to be normally wholly inside said housing;
>
> a plunger, axially moveable within the barrel;
>
> an inner housing intermediate the outer housing and the barrel and plunger; and
>
> an energy source in communication with said inner housing,

wherein the inner housing is moveable by the energy source in three modes, namely

a first mode in which the inner housing acts on the barrel such that, in use, the plunger and barrel are movable axially so as to move at least part of said needle out of the outer housing;

a second mode in which the inner housing acts on the plunger but not the barrel such that, in use, said plunger is movable axially into said barrel so as to expel medicament through the needle; and

a third mode in which the inner housing acts on neither the plunger nor the barrel such that, in use, the plunger and barrel are able to retract in order to retract the needle into the outer housing.

Rejection Under 35 U.S.C. § 103(a)

Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bloomberg in view of U.S. Patent Application 2003/0000524 by Anderson et al. To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), the Examiner must show that 1) the references teach all of the elements of the claimed invention, 2) the references contain some teaching, suggestion or motivation to combine the references, and 3) the references suggest a reasonable expectation of success. See MPEP § 2142; see also, In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); In re Kotzab, 217 F.3d 1365, 55 USPQ2d 1313 (Fed. Cir. 2000).

Anderson discloses a medicament dispenser (an inhaler) including a dispensing mechanism that is actuated by the application of non-mechanical energy. One embodiment of this invention recites the use of compressed air as the source of non-mechanical energy.

Applicant respectfully asserts that the Examiner has failed to establish a *prima facie* case of obviousness for at least the following reasons. Firstly, neither Bloomberg nor Anderson disclose an element equivalent to the inner housing element 7 of the present invention that is operable to act on both the barrel and the plunger of an injection device. Secondly, the use of an electric motor in the Bloomberg device is described at col. 1, line 65 - col. 2, line 5 as follows:

> [A]n electric motor . . . controlled by means of an electronic device. The electric motor is by means of a transmission mechanism connected to the displacement device, for accomplishing its displacement movements in a sequence determined by means of the control device for loading the injection syringe, as well as for insertion and injection.

These controlled sequences of displacement movements involve different parts, namely the inner part and the middle part moving in opposite directions. This movement is achieved with the use of two threaded screws that are driven by means of the electric motor. The screws are geared such that they rotate in opposite directions. It would be impractical to use compressed air to accomplish this simultaneous movement of components in opposite directions. Accordingly, there is neither a motivation to combine these references nor an expectation that such a combination would be successful.

For at least these reasons, the combination of Bloomberg and Anderson fails to support a *prima facie* case of obviousness. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claim 18 is new and recites a method of delivering an injection. As recited by Claim 18, in a first mode the barrel and plunger of an injection device are moved by an inner housing, in a second mode the plunger but not the barrel is moved by the inner housing, and in a third mode the inner housing acts on neither the plunger nor the barrel. As the cited references do not disclose such features it is submitted the Claim 18 should be allowed. In particular, the cited references fail to disclose at least the following italicized features of independent Claim 18:

18. (New) A method of delivering an injection comprising the steps of:

providing an injection device comprising:

a barrel for holding a dose of a medicament;

a needle at one end the barrel, the needle and barrel being such that at least part of the needle is axially moveable in and out of a outer housing but is biased to be normally wholly inside the outer housing;

a plunger, axially moveable within the barrel;

an inner housing intermediate the outer housing and the barrel and plunger; and

an energy source which acts on the inner housing;

activating the energy source;

moving the inner housing by means of the energy source;

in a first mode, moving the barrel and the plunger axially by means of the inner housing, wherein at least a part of the needle is moved out of the outer housing;

in a second mode, moving the plunger axially by means of the inner housing, wherein the plunger moves into the barrel causing medicament to be expelled through the needle, and wherein the barrel is not moved by the inner housing, wherein the inner housing acts on neither the plunger nor the barrel;

in a third mode, allowing the needle to retract to its biased position wholly inside the outer housing.

Based upon the foregoing, Applicant believes that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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